

In the Claims:

Please amend claims 16, 19 and 22 as follows:

B5 16. (Amended) The corn plant of claim 15, further comprising a nuclear or cytoplasmically-inherited gene conferring male sterility.

B6 19. (Amended) The tissue culture of claim 18, wherein the regenerable cells are in the form of protoplasts or callus cells.

B7 22. (Twice Amended) The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

II. RESPONSE TO OFFICE ACTION

A. Status of the Specification

The specification has been amended to correct deficiencies relating to information for the deposit of seed for the claimed inbred. A marked copy of the amendments is provided in **Appendix A**.

B. Status of the Claims

Claims 1-31 were filed with the original application. Claims 16, 19 and 22 were amended herein. A marked copy of the amendment is provided in **Appendix A**. A clean copy of the pending claims following entry of the instant amendment is provided in **Appendix B**. Claims 1-31 are now pending and presented for reconsideration.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claims 3, 4, 14 and 21-26 under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out the subject matter which Applicant regards as the invention.

(1) The Action rejects claims 1-31 as lacking an ATCC accession number. In response, Applicants note that the accession number was inserted in the claims in the Preliminary Amendment previously filed in the case. It is thus believed that the rejection is moot.

(2) The Action rejects claims 3 and 4 as broadening the claim from which they depend. Applicants respectfully traverse.

Claims 3 and 4 do not broaden the scope of claim 2. Claim 2 is directed to a population of seed of the corn variety I015036. Claim 3 further defines this claim by specifying "[t]he population of seed of claim 2, further defined as an essentially homogeneous population of seed." Claim 3 thus defines a further characteristic of the population of claim 2. While claim 2 is directed to a population of the corn variety I015036, it is not necessary that the population be an essentially homogeneous population of seed. The population may potentially include a small amount of other seed, yet still comprise a population of seed of corn variety I015036. Claim 3 thus further defines the scope of claim 2 and is not indefinite.

Claim 4 similarly recites "[t]he population of seed of claim 2, further defined as essentially free from hybrid seed." Once again, the population of claim 2 might contain a small amount of contaminating hybrid seed and thus not be essentially free from hybrid seed, yet still comprise a population of seed of corn variety I015036. Therefore, claim 4 further defines the claim from which it depends and is not indefinite.

(3) The Action rejects claim 14 for recitation of "An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015036." Applicants respectfully traverse.

While it is true that I015036 seed can only produce I015036 plants, it is not required that a population of seed produced by growing I015036 seed contains only I015036 plants. For example, the collection of I015036 seed used to plant the population of I015036 plants may contain small amounts of other seed. Alternatively, other types of plants may grow within a population of plants that are grown, whether from I015036 seed or another type of seed, that were not necessarily intended to be grown, including weeds. As such, "essentially homogeneous" further defines the scope of the claim and the term as it is used is not indefinite.

(4) The Action rejects the claims for use of the term "nuclear or cytoplasmic gene." Applicants respectfully traverse.

Applicants traverse the rejection but note that the claim has been amended to recite a cytoplasmically-inherited gene conferring male sterility. It is believed that the rejection is now moot.

(5) The Action rejects claim 19 for recitation of "wherein the regenerable cells comprise protoplasts or callus." In response it is noted that the claim has been amended. It is believed that the rejection is now moot.

(6) the Action rejects claims 21 and 22 as allegedly not specifying how many crosses are performed. Applicants respectfully traverse.

At page 21, lines 5-6, the specification defines "crossing" as "The pollination of a female flower of a corn plant, thereby resulting in the production of seed from the flower." In light of this definition, and the claim language, it is clear that crossing in claim 21 is done one time. For

example, claim 21 specifies that after the crossing "seed is allowed to form." If multiple generations were involved, the claim would have to specify that after the seed is formed, it is planted and crossing takes place again. The claim is thus not indefinite. With respect to claim 22, the claim has been amended and thus it is believed that the rejection is moot.

In view of the foregoing, removal of the rejections under 35 U.S.C. §112, first paragraph is respectfully requested.

D. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description

The Action rejects claims 3, 4, 14 and 24-31 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to convey that Applicants were in possession of the claimed invention. Applicants respectfully traverse.

With respect to populations of seed of corn variety I015036, the Action suggests that in populations of seed comprising less than 100% I015036 seed the identity of the remaining seed is unknown. In response, Applicants first note that the Patent Office has issued more than 75 patents including claims to populations of corn seed of a given variety. Thus, the impetus for the instant rejection is not understood. It is further noted that the identity of any other seed included in a population of seed of variety I015036 is irrelevant. The fact that claimed populations of seed of variety I015036 may not be completely purified, and thus may comprise unspecified contaminant seed, does not take the claim out of compliance with the written description requirement.

Under the reasoning in the Action, any open language in a claim would be impermissible because it is unknown what other components might be contained in a given composition. For

example, a claim to a composition "comprising ingredient A," would lack written description because there is an infinite scope of other possible ingredients that could be added to the composition. Here, the claims are directed to populations of seed of variety I015036 that may or may not be completely purified. As set forth above, however, this is irrelevant to written description as seed of variety I015036 has been fully described and the identity of any contaminant seed is irrelevant to the scope of the claim.

Applicants have also fully described the other subject matter cited in the Action in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. In particular, the specification provides a description of sufficient structural characteristics of hybrid plants having inbred corn plant I015036 as one parent to satisfy the written description requirement. For example, the specification provides a detailed description of hybrid 8012681, which was produced with I015036 as one inbred parent. Table 5 of the specification gives the morphological traits of 8012681. Further, the SSR marker profile and isozyme marker profiles for hybrid 8012681 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of the genetic and morphological characteristics of I015036 in the specification, as well as the fact that any hybrid derived from I015036 will contain exactly half of its genes from I015036, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant I015036 in compliance with the written description requirement.

The specification further provides an SSR genetic marker profile of I015036 in Table 6. Because corn plant I015036 is an inbred corn plant, all hybrid plants having I015036 as a parent will contain these same SSR genetic markers and thus will be genetically distinct and identifiable from any other corn plant on this basis. That is, because I015036 is an inbred corn plant, all

hybrid corn plants derived therefrom must inherit exactly half of the genetic material of corn plant I015036.

The Federal Circuit has noted that such shared identifiable structural features possessed by members of a genus is important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*” (emphasis added)). Here, all of the members of the claimed genus of hybrids having I015036 as one parent share the identical structural feature of having the genetic complement of I015036. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

The Action also rejects claims to single locus conversions of corn plant I015036 on the basis that I015036 may allegedly be altered in any of its traits and that the specification does not describe “single locus conversions and single transgenes that have the ability to alter any given maize plant trait.” In response, it is first noted that the relevant claims are directed to corn plant I015036 which further comprises a single locus conversion. Such a “single locus converted (conversion) plant” is defined at page 23, lines 6-12 of the specification as follows:

[p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". Applicants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant I015036 by way of the descriptions of I015036. To hold otherwise would be to limit Applicants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)).

The rejection also ignores the substantial description in the specification supporting single locus conversions of I015036. For example, at pages 29-31, the methodology for creating single locus converted plants is described. At pages 31-33, numerous single locus traits for creation of single locus converted plants are described, such as those conferring male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. Many of these traits are also described in PCT Application WO 95/06128, the disclosure of which is incorporated by reference in the current specification. The specification also provides examples of genes conferring male sterility, including those disclosed in U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No. 5,625,132, and U.S. Patent No. 4,727,219, the disclosures of which were also incorporated by reference in the current application.

At pages 31-32, detailed methodology and compositions are described for introducing male sterility into inbred corn plant I015036, including the use of one or more male-fertility restorer genes. Examples of such male-sterility genes and corresponding restorers are given by way of U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, each of the disclosures of which were incorporated by reference in the current application. Methods for selection of dominant single locus traits are also described at page 30, for example, such as a herbicide resistance trait.

Further described at page 33 of the specification is the preparation of transgenic single locus conversions, including those created by electroporation (U.S. Patent No. 5,384,253), electrotransformation (U.S. Patent No. 5,371,003), microprojectile bombardment (U.S. Patent No. 5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765).

The use of a single locus trait conferring resistance to the herbicide glyphosate is described at page 33-34, including a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060), as well as a mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103). Methods for the use of these single locus conversions are also described. Further described, are numerous other single locus traits for preparation of single locus conversions, including a selectable marker gene encoding phosphinothricin acetyl transferase (PPT) (*e.g.*, a bar gene), a gene encoding an endotoxin from *Bacillus thuringiensis* (Bt), and the waxy characteristic, each of which are well known to those of

skill in the art. Still further, the specification describes, at pages 35-36, the origin and breeding history of an exemplary single locus converted plant, including all steps necessary for the preparation of the single locus converted plant.

The detailed description of single locus traits and of corn plant I015036 is more than adequate to provide a written description of single locus conversions of corn plant I015036. The specification itself defines a single locus converted plant comprises essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, e.g., I015036. While Applicants have not described every possible single locus conversion that could be introduced into corn plant I015036, this is not required under the written description requirement. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). As such, Applicants have fully complied with the written description and removal of the rejection under 35 U.S.C. §112, first paragraph, is thus respectfully requested.

E. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

The Action rejects claims 1-31 under 35 U.S.C. §112, first paragraph, for lack of a seed deposit.

In response, Applicant notes that a deposit of 2,500 seeds of the variety I015036 was made with the ATCC. The deposit was made in accordance with the terms and provisions of 37 C.F.R. §1.808 relating to deposits of microorganisms. The deposit was made for a term of at least thirty years or at least five years after the most recent request for furnishing of a sample of the deposit is received by the depository or for the effective life of the patent, whichever is longer. A declaration certifying that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809 is attached hereto under **Appendix C**.

The rejected claims have each been amended, either directly or by way of dependency upon an amended claim, to recite the accession number for those seeds of the inbred corn plant I015036 which have been deposited with the ATCC. The claim amendments do not narrow the claims and accordingly Applicant does not intend to disclaim any subject matter through the amendments. The specification has also been amended to include the accession number of the deposit and the date of deposit.

In light of the foregoing, Applicant respectfully requests removal of the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

F. Rejection of Claims Under 35 U.S.C. §102(e)/103(a)

The Action has rejected claims 1-5, 7-10, and 12-31 under 35 U.S.C. §102(e)/103(a) as allegedly anticipated or, in the alternative, obvious over U.S. Patent 6,043,417. Applicants respectfully traverse.

The rejection is made based on the allegation that the plant of the cited patent *may* be the same as the claimed plants or render the instant plant obvious. In response, Applicants first note that it is the burden of the Office in an anticipation rejection to show that each and every element as set forth in the claim is found in the prior art. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). This has not been done and the rejection must therefore fail.

To the extent that alleged unexpressed inherent characteristics form the basis of an anticipation rejection, it is noted by Applicants that these characteristics must necessarily flow

from the disclosure. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."). Here, all that is stated in the Action is that the claims might be anticipated without any showing that this is the case. The Action has thus clearly failed to meet the burden under 35 U.S.C. §102.

Similarly, in order to establish a *prima facie* case of obviousness under 35 U.S.C. §103, three criteria must be met: (1) there must be some motivation or suggestion in the cited prior art or in the knowledge generally available to one of skill in the art to combine the teachings to arrive at the invention, (2) there must be a reasonable expectation of success, and (3) the prior art must teach or suggest all claim limitations. *See In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991), *see also*, M.P.E.P. § 2142. All three of these criteria are missing in the instant rejection. First, there is no motivation or suggestion in the prior art to arrive at the invention and no rationale for such a motivation has been alleged in the Action. The rejection thus relies on an "obvious to try" type rationale. This approach has been rejected by the Federal Circuit. *See In re O'Farrell*, 853 F.2d 894, 903. Second, one of skill in the art would have no reasonable expectation of success in plant breeding to arrive at the invention. For example, there is no indication or showing in the Action that a second corn plant that could be used to produce plants within the scope of the claims even exists, let alone the motivation for one of skill in the art to do so. Finally, the Action has not shown that the prior art teaches or suggests all of the claim